



FEDERAL MINISTRY
OF SOCIAL SECURITY AND GENERATIONS

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Vienna, 5th July 2002

Dear Dr. Stratmoen:

The Austrian Veterinary Services of the Federal Ministry of Social Security and Generations thank you for the report of the audit that was conducted between March 12 and March 22, 2002.

As a consequence of the audit, the establishments Est. O2 and O8, which were audited by Dr. Faizur Choudry, were removed from the list of certified establishments.

Regarding this fact the Austrian Veterinary Services will not re-certify one of these establishments, before conducting a re-certification audit.

The Veterinary Services got information by the Provincial government of Upper Austria, that Establishment O 2 will not apply for US-certification for the time being.

/2

Establishment O 8 presented a catalogue of measures in order to show how and in which period of time they will take all the corrective actions. Among other things this catalogue of measures includes constructional measures, corrections relating to hygiene and development of HACCP.

After the implementation and realisation of this concept and if the establishment applies for a US re-certification, Austria will conduct a complete re-certification audit – as requested in the letter from April 30, 2002 – and will provide FSIS with documentation of the audit.

Independent from this, the deficiencies according to the Austrian Meat and Hygiene Law, in connection with the implementation of EC Directive 64/433 noted in the audit are in the process of correction and improvement (e.g. constructional problems).

Nevertheless the Veterinary Services would like to provide some written comments and corrections (written in italics and in bold types) regarding information in the draft report:

Entrance Meeting (page 3)

- The name of the Head of Department 7 of the Veterinary Services for Meat **Hygiene/Residue Control/Poultry Hygiene/Raw Material of Animal Origin is Dr. Peter-Vitus Stangl.**
- Dr. Andrea Höflechner, Veterinary Medical Doctor, Department 4 (since July 1, Department 8)

Please indicate the correct name of Dr. Peter-Vitus Stangl (see also page 19 and 20 of the report).

Government oversight (page 4)

The veterinarians that actually perform the daily inspection are paid by the provincial government, because they are provincial employees (it is correct that they are not hired and paid by the federal government).

Veterinary services are organized in indirect federal administration (**indirect federal administration**). In other words, the federal administration is undertaken by the provincial authorities under the authority of the federal ministers (Legal Basis: Federal Constitution Law, B-VG), who is authorized to issue orders.

Orders from federal ministers in indirect federal administration must always be directed to the federal provincial governor who **must** ensure that in indirect federal administration the federal regulations are complied with also by the provincial authorities under his responsibility (district administrative authorities, mayors).

Second paragraph:

Besides participation in development and negotiation of EC legislation, interpretation and clarification of international and national law, one of the most relevant responsibilities of the federal government is – and this is a very important scope of duties of the Federal Ministries – to implement EC Legislation into Austrian Law.

Third paragraph:

- **Austria** consists of ~~the~~ nine provinces.

Laboratory Audits

Second paragraph, page 5 and Attachment D:

The **name** of the laboratory, which was audited on March 15, 2002, was the **Federal Institute for Veterinary Medicine in Mödling** (or Moedling).

First paragraph, page 6:

It is not correct that Austria's microbiological testing for E.coli and Salmonella is being performed exclusively in private laboratories! Each laboratory, analysing microbiological samples, has been approved officially, this applies to private laboratories as well. The legal basis for the approval of the laboratories can either be Article 27 of the Meat Inspection Act or Article 42, 49 or 50 of the Food Act.

Microbiological testing for E.coli and Salmonella is also done in State laboratories. Since June 1, 2002 it is done by the Agency –Austrian Agency for Health and Nutrition -, where all State laboratories (veterinary labs, human labs and food labs) are included. The Laboratory in Perg, which is testing E.coli and Salmonella for US-certified establishments, is a private one, but approved officially under § 50 of the Food Act.

Referring to the concern that timely analyses are critical for hormones, antibiotics and sulfonamides:

With regard to the available staff and equipment the analyses are performed as quick as possible to ensure an effective residue control system. Nevertheless, there is no EC - Regulation or Decision where it is required to perform and finalize the analyses of official samples for monitoring of residues in a certain time period.

Also from the technical point of view no problems occur for the stability of the substances mentioned in the draft report.

The laboratory tries hard to improve this, although problems regarding staff resources and technical equipment make this difficult. It is the aim of the lab to fulfil all criteria in order to ensure the quality and comparability of the analytical results in the official residue control.

Referring to the concern that the standards book was not properly maintained:

The system of record keeping is in accordance with the accreditation standard ISO/IEC 17052, which has been approved by the EC. As a result of a control by the Community Reference laboratory Fougères in June 2002, the standards book presented was fully accepted.

The way of keeping this book is in line with the ISO 17025. When the technical staff prepare the standard solutions it is not necessary to supervise or verify and sign this in the standards book before use, on condition that the level of education of the technical staff in the lab is high.

The registration of the lot-number of the standards and the date of purchase will be done in the future. For the registration of the pages of the standards book, which were already archived, a new system will be developed.

Referring to the concern that proficiency tests for quality assurance programs were not performed for sulfonamides:

First of all some clarification: *E. coli* and *Salmonella* are not investigated in the laboratory approved for official residue control; these two terms should be deleted.

In each batch at least one spiked control sample and if necessary a negative control sample or samples with different internal standards are analysed in order to control the whole procedure of analyses. According to relevant EC-regulations and the accreditation standard ISO 17025 additional control samples are not obligatory.

The last ring test for sulfonamides where the lab participated was organised by FAPAS, United Kingdom, in autumn 1999. Since this time neither the Community Reference Laboratory Fougères nor FAPAS organised ring tests for this group of substances.

Sanitation Controls (page 6 to 8)

In both establishments the written SSOP and the identification in the daily pre-operational and operational sanitation deficiencies will be revised and improved.

Animal Disease Controls (page 8/9)

It is not correct that Austria shares a border with a country or countries that are not free from Foot and Mouth Disease (FMD):

Although FMD occurred in some countries of the European Union, there was no outbreak of FMD in Germany, a neighbouring country. The third countries, which have a border to Austria, are free from FMD as well! **The conclusion of these facts is that Austria is not a substantial risk for FMD!**

Residue Controls (page 9/10)

See the comments to the chapter "Laboratory Audits", page 5/6.

On farm (page 9/10)

Page 10: additional information to paragraph 2:

The Austrian Veterinary Services would like to emphasize that it is forbidden to slaughter animals during the withdrawal period, the only thing possible is to kill them for animal welfare reasons.

Conclusions (page 16)

As a result of this audit the Department 3 (since July 1: Department 7) of the Veterinary Services organized a meeting (May 14, 2002) with governmental experts on meat hygiene of all provinces of Austria in order to discuss the lack of oversight in the meat inspection system.

According to the problems of HACCP implementation in the establishments a workshop is scheduled at the beginning of autumn. The participants will be experts sent by the governmental officials of the Provinces.

Foreign Country Laboratory Review (Review date 03/15/02)

The City&Country is **Mödling (or Moedling)**

Name of foreign officials:Dr. Josef Flatscher, Deputy Director

Statements to the comments see chapter "Laboratory Audits"

Foreign Country Laboratory Review (Review date 03/14/02)

Name of foreign officials: **Dr. Peter-Vitus Stangl** (and not Dr. Mikula)

Referring to the concern that the proficiency test for quality assurance program were not performed for E.coli and Salmonella:

The proficiency tests for quality assurance program will be implemented for E.coli and Salmonella at the moment one of the establishments ask for a US-recertification. In the same way it is scheduled that the carcass selection will be done randomly.

For the Federal Minister:
Dr. DAMOSER

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of the copy:

Pausmeang